

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant: Rourke M. Yeakley

Application No.: 10/617,166

Filed: July 9, 2003

Group/Art Unit: 3753

Title: Pre-dosed oral liquid medication
dispensing system

Examiner: Melvin A. Cartagena

Attorney Docket No: YEAR102

APPEAL BRIEF (37 CFR §1.192)

Assistant Commissioner for Patents
P.O. Box 1450
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ATTENTION: Board of Patent Appeals and Interferences

This Brief is in furtherance of the Notice of Appeal filed in this case on April 24, 2008.

The fees required under 37 CFR 1.17(f) are dealt with in the accompanying
TRANSMITTAL OF APPEAL BRIEF.

This Brief is transmitted in triplicate (37 CFR §1.192(a)).

I. REAL PARTY IN INTEREST

Not applicable (the Applicant is the real party in interest).

II. RELATED APPEALS AND INTERFERENCES

Appellant and the appellant's legal representative are not aware of any other appeals or interferences that will directly affect or be directly affected by or having a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

The status of the claims in his application are:

A. Total Number of Claims in Application.

Application contains seventeen claims numbered 1-17.

B. Status of All the Claims.

1. Claims canceled: Claims 2, 4, 5, 10, 12, and 13.
2. Claims withdrawn from consideration, but not canceled: Claim 17.
3. Claims pending: Claims 1, 3, 6-9, 11, and 14-16.
4. Claims allowed: None.
5. Claims rejected: Claims 1, 3, 6-9, 11, and 14-16.

C. Claims on Appeal.

The claims on appeal are: Claims 1, 3, 6-9, 11, and 14-16.

IV. STATUS OF AMENDMENTS (37 CFR §1.192(c)(4))

No amendments were filed subsequent to the final rejection.

V. SUMMARY OF INVENTION (37 CFR §1.192(c)(5))

Medication cannot necessarily be effectively administered in all locations due to the fact that in many locations individuals do not know how much medication to impart to reach the desired dosing requirements for efficacy while also preventing damage to the individual.

Another problem that occurs is that, in some instances, the ability to take the medication cannot be effectively performed because of a lack of dispensatory materials at the designated location. (page 1, paragraph [0002]). The present invention is a liquid medication dispensing system for dispensing measured doses of selected medications comprising an ampule containing a pre-selected quantity of a selected medication (page 4, paragraph [0009]).

In one embodiment, for example, the embodiment shown in Figs. 1A, and 2-4, the present invention has an ampule 12 and a container 22. Contained within ampule 12, medication 14 is in a dry powdered form and is separated from a reconstituting liquid 32 by a rupturable membrane 30. This rupturable membrane 30 divides the ampule 12 into a medication chamber 28 and a reconstituting chamber 26 (page 8, paragraph [0020]).

The medication 14 is stored as a powder and the reconstituting liquid 32 is held in a separate chamber 26 by a rupturable membrane 30. In order to rupture this membrane 30 the ampule 14 must be bent so as to produce sufficient pressure against the membrane 30 so as to cause the membrane 30 to break and for the liquid 32 and the medication 14 to be mixed. The ampule 12 can then be punctured by a puncturing device to produce an opening 16 sufficient in size to allow delivery of the medication to the intended recipient. Once the opening 16 has been made in the ampule 12, the medication may be delivered by simply squeezing the ampule 12 to force the medication out of the ampule 12 through the opening 16. See page 9, paragraph [0022] and page 9, paragraph [0023].

In the preferred embodiment, the expulsion of medication through the opening 16 is enhanced by the inclusion of a quantity of an expelling material. In the preferred embodiment, this is simply a quantity of air that is included within the ampule 12 and is configured to increase the efficacy of expelling material out of the ampule 12 (see page 9, paragraph [0024]).

Being configured to increase the efficacy of expelling material out of the ampule 12, said quantity of air is pressurized. Depending upon the specific medications that are utilized, an additional rupturable membrane 30 may be required to separate the expelling material from the remainder of the medications that are held in the ampule.

VI. GROUNDS OF REJECTION TO BE REVIEWED (37 CFR §1.192(c)(6))

A. Whether claims 1, 3, and 6-8 are anticipated (§102(b)) by U.S. Patent 4,548,601 (Lary).

B. Whether claims 9, and 14-16 are anticipated (§102(b)) by U.S. Patent 4,059,109 (Tischlinger).

C. Whether claim 11 is obvious (§103(a)) over U.S. Patent 4,059,109 (Tischlinger) in view of U.S. Patent 5,286,257 (Fischer).

VII. GROUPING OF CLAIMS (37 CFR §1.192(c)(7))

<u>Group</u>	<u>Claims</u>
A	1, 3, and 6-8
B	9, and 14-16

VIII. ARGUMENT (37 CFR §1.192(c)(8)(iv))

Appellant submits that, for the following reasons, the pending claims 1, 3, 6-9, 11, and 14-16 are neither disclosed nor taught by the cited references, and are therefore neither anticipated nor rendered obvious by the cited references; and consequently are patentable.

A. Claims 1-4, 6, and 8 are not anticipated by Lary.

1. The Examiner rejected claims 1, 3, and 6-8 under §102(b) as being anticipated by Lary.

2. “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). “The identical invention must be shown in as complete detail as contained in the . . . claim.” *Richardson v. Suzuki Motor Co.*, 828 F.2d 1226,1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). MPEP § 2131.

3. Claim 1 of the current application specifically states “a pre-selected quantity of a selected liquid oral medication” is contained within the ampule of the current application. The prepackaged, injectable pharmaceutical and hypodermic needle combination as described by Lary, neither teaches nor suggests oral medication.

4. Claim 1 of the current application further states:

“a designated quantity of an expelling material, said ampule configured to laterally compress when a designated quantity of pressure is applied to said ampule and to force said expelling material and said medication out of said ampule through said opening”

Additionally from paragraph 24:

“[0024] In the preferred embodiment, the expulsion of medication through the opening 16 is enhanced by the inclusion of a quantity of an expelling material 50. In the preferred embodiment this is simply a quantity of air that is included within the ampule 12 and is configured to increase the efficacy of expelling material out of the ampule 12. Depending upon the specific medications that are utilized, an additional rupturable membrane 30 may be required to separate the expelling material from the remainder of the medications that are held in the ampule.”

The statement above illustrates the essential role of the expelling material that cannot be ignored or discounted. The expelling material is used to aid in the expulsion of medicine from the ampule in some cases variables such as viscosity, suspension vs. solution, etc., require the expellant and/or additional membrane. The expelling material, acting as a propellant, is configured to provide locomotive force to the medication. The invention taught by Lary does not and cannot include this limitation.

5. The current application is not an injection device, Applicant believes this is readily apparent in the application. The prepackaged, injectable pharmaceutical and hypodermic needle combination as described by Lary is incapable of performing the function of the current application. With the expelling material being air, acting as a propellant, serious harm or death could occur by injecting air into an individual. Due to this imminent damage to the user, expelling material cannot exit the ampule utilizing the same aperture as medication in the Lary device.

6. Further, the prepackaged, injectable pharmaceutical and hypodermic needle combination as described by Lary does not teach nor suggest expelling said expelling material and said medication out of said ampule through said opening.

7. As such, Lary does not anticipate claim 1, and therefore claim 1 and all of the claims that depend therefrom (claims 3, and 6-8) are not anticipated.

B. Claims 9, and 14-16 are not anticipated by Tischlinger.

1. The Examiner rejected claim 9 under §102(b) as being anticipated by U.S. Patent 4,059,109 (Tischlinger).

2. Claim 9 of the current application states:

“a designated quantity of an expelling material, said ampule configured to compress when a designated quantity of pressure is applied to said ampule and to force said expelling material and said medication out of said ampule”

3. The mixing and dispensing disposable medicament injector as described by Tischlinger is incapable of performing the function of the current application, it is impossible for the Tischlinger device to carry out any function of the current application. The current application is not an injection device, Applicant believes this is readily apparent in the application. There are no needles on the ampule of the current application, to include needles would completely change the functionality and render the item useless for its intended function. The expelling material is used to aid in the expulsion of medicine from the ampule, in some cases variables such as viscosity, suspension vs. solution, etc., require the expellant and/or additional membrane. The expelling material, acting as a propellant, is configured to provide locomotive force to the medication. The invention taught by Tischlinger does not and cannot include this limitation.

4. The inclusion of the expelling material (i.e., a propellant) from the current invention would render the Tischlinger device inoperable. The ampule of the current application exhibits no plungers as seen in the mixing and dispensing disposable medicament injector as described by Tischlinger. The expelling material would provide a restive force on the plunger of the Tischlinger device opposite direction of intention, resulting in either pushing the plunger

completely out or moving the plunger a distance proportional to the force of pressure contained in the cylinder. Expelling material intrinsically prohibits the use of plunger actuated devices due to the resistive force it would apply.

5. Tischlinger does not teach nor suggest any expelling material. Claim 9 of the current application clearly states three different materials contained within the ampule:

“a closed, squeezable, puncturable ampule having a first chamber configured to hold a premeasured amount of a selected medication stored in a powdered form therein, and a second chamber configured to hold a premeasured amount of a reconstituting liquid therein, “

and

“a designated quantity of an expelling material, said ampule configured to compress when a designated quantity of pressure is applied to said ampule and to force said expelling material and said medication out of said ampule.”

6. This is in stark contrast to the mixing and dispensing disposable medicament injector as described by Tischlinger which only discloses a dry and liquid medicament. Tischlinger does not anticipate the present invention in claim 9 because each and every element as set forth in said claim is not found in Tischlinger.

7. As such, Tischlinger does not anticipate claim 9, and therefore claim 9 and all of the claims that depend therefrom (claims 14-16) are not anticipated.

C. Claim 11 is not obvious over Tischlinger in view of Fischer.

1. “Non-analogous prior art”

a. The Federal Circuit has stated that art is analogous only “if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem.” *In re Clay*, 23 USPQ2d 1058 (Fed. Cir. 1992). In the *In re Clay* case, the subject claims were directed to a process that improved removal of oil products from storage tanks. The Examiner in that case cited a patent directed to improving production of oil from underground formations. The Federal Circuit held that the cited patent as not analogous art even though the cited patent and subject application both related to the oil industry.

b. In this case, injection devices, devices for mixing and brushing on dental medicaments, and the combination thereof is not reasonably pertinent to the particular problem with which the inventor is involved. An inventor of a premeasured oral medicine ampule would not have found the matter injectors or dental brushing tools to logically commend itself to the Inventor's attention in considering his portability and dosing problems.

c. The Tischlinger in view of Fischer reference is non-analogous prior art. While Tischlinger, Fischer, and the present invention may all be used to contain some type of medication, that is not the standard here. The fact remains that an inventor of an orally consumed medication ampule would not have found the matter of injections to logically commend itself to the inventor's attention in considering his portability and dosing problems. Internal injections have nothing to do with pre-measuring, and administering of oral medication.

2. Prima Facie Case

b. "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)." MPEP § 706.02(j).

c. **Suggestion or motivation.** The law regarding obviousness is clear--any modification of the prior art must be suggested or motivated by the prior art. *In re Fitch*, 972 F.2d 1260, 23 USPQ2d 1780, 1783-4 (Fed.Cir. 1992). There is no motivation whatsoever provided by Tischlinger in view of Fischer to provide the present application. The injector as described by Tischlinger in view of Fischer is incapable of performing the function of the current application, it is impossible for the Tischlinger in view of Fischer device to carry out any function of the current application. The current application is not an injection device. There are no needles on the ampule of the current application, to include needles would completely change the functionality.

d. With the expelling material being air, acting as a propellant, serious harm or death could occur by injecting air into an individual. Due to this imminent damage to the user, expelling material cannot exit the ampule utilizing the same aperture as medication in the Tischlinger in view of Fischer device.

e. Further, the inclusion of the expelling material from the current invention would render the Tischlinger in view of Fischer device inoperable. The ampule of the current application exhibits no plungers as seen in the injector as described by Tischlinger in view of Fischer. The pressurized expelling material, acting as a propellant, would provide a restive force on the plunger of the Tischlinger in view of Fischer device opposite direction of intention, resulting in either pushing the plunger completely out or moving the plunger a distance proportional to the force of pressure contained in the cylinder. Expelling material intrinsically prohibits the use of plunger actuated devices due to the resistive force it would apply. The expelling material is used to aid in the expulsion of medicine from the ampule in some cases variables such as viscosity, suspension vs. solution, etc., require the expellant and/or additional

membrane. The expelling material, acting as a propellant, is configured to provide locomotive force to the medication. The invention taught by Tischlinger in view of Fischer does not and cannot include this limitation.

f. It is the Appellant's position that the Examiner has used improper hindsight reconstruction, picking and choosing features in the prior art in order to piece together prior art references which bear the similar elements as the present invention. When a suggestion or motivation to combine selected elements of prior art references is not supplied by the prior art, the incentive to make such a combination can only come from improper hindsight reconstruction using the applicant's specification. *In re Fritch*, 972 F.2d 1260, 23 USPT2d 1780, 1784 (Fed.Cir. 1992), (in part quoting from *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988)). Likewise, to draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction -- an illogical and inappropriate process by which to determine patentability. *W.L. Gore & Assoc. v. Garlock, Inc.* 721 F.2d 1132, 1138, 220 USPQ 303, 312-13 (Fed. Cir. 1983). The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138, 227 USPQ 543, 547 (Fed. Cir. 1985).

g. The Appellant further argues that there is no suggestion, no motivation, no desirability and no motivating suggestion to make the Examiner's suggested combination. One would not look to technologies involving injection apparatuses, an inventor of a premeasured oral medicine ampule would not have found the matter of injectors or dental bushing tools to logically commend itself to the Inventor's attention in considering his portability and dosing problems. Therefore, it is not logical to combine the elements of Fischer and Tischlinger to produce a functional equivalent of the present application. As such, the present invention is non-obvious.

3. **Reasonable expectation of success.** Reasserting the argument above, there is no expectation of success to combine the elements of Fischer to Tischlinger as doing so would cause serious bodily harm to individuals using the combined device, and the combined device of Fischer to Tischlinger would not perform the same function of the current application. It is impossible for the combination of Fischer to Tischlinger to function as the present application. As such, there is no reasonable expectation of success in combining Fischer to Tischlinger to produce a functional equivalent of the present application.

4. **Teach or suggest all the claim limitations.** Neither Tischlinger nor Fischer contain all the limitations of the present application as taught in Claim 9.

a. Claim 9 which claim 11 depends upon states:

“said first chamber separated from said second chamber by a pressure sensitive breakable membrane, said membrane configured to be broken when a preselected quantity of

pressure is applied to the membrane thus allowing said powder to be mixed with said reconstituting liquid and for said powder to be suspended within said reconstituting liquid and to allow said suspension to be dispensed from said ampule through an opening of a calibrated size located within said ampule when pressure is applied to said ampule;”

b. The appellant points out that neither Tischlinger nor Fischer contain the limitation that the membrane configured to be broken when a preselected quantity of pressure is applied to the membrane. Rather, the membrane is broken piercing an additional object through said membrane in the device of Tischlinger in view of Fischer. As such, the Examiner’s cited references do not teach or suggest all the claim limitations in claim 9, and therefore do not teach or suggest all the claim limitations in claim 11.

D. Conclusion of Argument

The Appellant submits that the independent claims 1 and 9, as well as their variously dependent claims, are in condition for allowance as being allowable over the cited references. Appellants submit, therefore, that the rejections to claims 1, 3, 6-9, 11, and 14-16 under §102/§103 have been overcome and should be overturned by the Board.

Reconsideration and allowance of the application is respectfully requested.

DATED this 13th day of June, 2008.

Very respectfully,

/Frank J. Dykas/
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CERTIFICATE OF EFS-WEB TRANSMISSION UNDER 37 CFR 1.8

I HEREBY CERTIFY that this correspondence is being transmitted to the United States Patent and Trademark Office by EFS-Web on the date below.

DATED: This 13th day of June, 2008.

/Julie L. O'Tyson/
Julie O'Tyson

IX. APPENDIX OF CLAIMS (37 CFR 1.192(c)(9))

The text of the claims on appeal is as follows:

1. An oral liquid medication dispensing system for dispensing measured dosages of selected oral medications comprising:

a puncturable, compressible ampule having a closed body containing a pre-selected quantity of a selected liquid oral medication therein, said ampule configured to hold a premeasured quantity of said selected medication, and to dispense said quantity of medication through an opening in said ampule after said opening is formed within said ampule and a designated quantity of pressure is applied to said ampule, and

a calibrated puncturing device configured to create an opening of a desired size within said ampule, and

a designated quantity of an expelling material, said ampule configured to laterally compress when a designated quantity of pressure is applied to said ampule and to force said expelling material and said medication out of said ampule through said opening.

2. (Canceled)

3. The oral liquid medication dispensing system of claim 1 wherein said expelling material is air.

4. (Canceled)

5. (Canceled)

6. The oral liquid medication dispensing system of claim 3 further comprising a container configured to hold said ampule and said puncturing device, in a sealed environment.

7. The oral liquid medication dispensing system of claim 6 wherein said puncturing device is a portion of said container.

8. The oral liquid medication dispensing system of claim 7 wherein said container is a generally rectangularly shaped box configured to hold said ampule therein, said container having a bottom portion said bottom portion defining at least one puncturing device therein.

9. A self-contained dispensing system for dispensing measured amounts of oral medication stored in a powdered form but delivered in a liquid form, said system comprising:

a closed, squeezable, puncturable ampule having a first chamber configured to hold a premeasured amount of a selected medication stored in a powdered form therein, and a second chamber configured to hold a premeasured amount of a reconstituting liquid therein, said first chamber separated from said second chamber by a pressure sensitive breakable membrane, said

membrane configured to be broken when a preselected quantity of pressure is applied to the membrane thus allowing said powder to be mixed with said reconstituting liquid and for said powder to be suspended within said reconstituting liquid and to allow said suspension to be dispensed from said ampule through an opening of a calibrated size located within said ampule when pressure is applied to said ampule ; and

a calibrated puncturing device, said calibrated puncturing device configured to produce a hole of a calibrated size within said ampule; and

a designated quantity of an expelling material, said ampule configured to compress when a designated quantity of pressure is applied to said ampule and to force said expelling material and said medication out of said ampule.

10. (Canceled)

11. The oral medication dispensing system of claim 9 wherein said expelling material is air.

12. (Canceled)

13. (Canceled)

14. The oral medication dispensing system of claim 9 further comprising a container configured to hold said ampule and said puncturing device, in a sealed environment.

15. The oral medication dispensing system of claim 14 wherein said puncturing device is a portion of said container.

16. The oral medication dispensing system of claim 14 wherein said container is a generally rectangularly shaped box configured to hold said ampule therein, said container having a bottom portion said bottom portion configured to contain at least puncturing device therein.

17. (Withdrawn) A method of dispensing premeasured amounts of a selected medication in a liquid form utilizing a system comprised of an ampule having a first chamber configured to hold a premeasured amount of a selected medication stored in a powdered form therein, and a second chamber configured to hold a premeasured amount of a reconstituting liquid therein, said first chamber separated from said second chamber by a breakable membrane; a puncturing device configured to create an opening of a desired size within said ampule; and a container configured to hold said ampule and said puncturing device, said system comprising the steps of:

opening said container;

removing said ampule from said container;

bending said ampule to rupture said membrane;

shaking said ampule to suspend said powdered medication within said reconstituting liquid;

puncturing said ampule with said puncturing device to form an opening; and

squeezing a portion of said ampule to dispense said medication to an intended beneficiary through said opening.